STATEMENT OF MICHAEL MCCAWLEY, CHIEF SCIENTIFIC OFFICER OF RESPIRATORY MANAGEMENT TECHNOLGY, BEFORE THE SUBCOMMITTEE ON AVIATION, COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE, U.S. HOUSE OF REPRESENTATIVES, ON EFFORTS TO PREVENT PANDEMICS BY AIR TRAVEL.

APRIL 6, 2005

Chairman Mica, Congressman Costello, and Members of the Subcommittee,

Good afternoon. It is a pleasure to be here before the committee today and testify on this important health issue of preventing pandemics by air travel. I am Dr. Michael McCawley, Chief Scientific Officer and co-founder of Respiratory Management Technology. I hold a doctorate in environmental health from New York University, a master's degree in engineering from West Virginia University and a bachelor's degree in zoology from George Washington University. For twenty seven years I worked as a Public Health Service Officer and scientist with the Centers for Disease Control and Prevention at the National Institute for Occupational Safety and Health, NIOSH, and retired from there three years ago. For twenty five years I have also been a Professor of Civil and Environmental Engineering at West Virginia University, where I have taught courses in air pollution and aerosol science. I have published over forty papers in the scientific literature, mainly on topics concerning aerosols, that is, particles in the air. I have been recognized with awards both from the government and from scientific organizations for my work on aerosols. As a team leader at NIOSH I supervised a group of researchers responsible for developing the methods for assessing airborne microorganism concentrations. The method developed, the N-6 sampler, is recognized as the gold standard for airborne microorganism detection. Members of this same team participated in the evaluation of the anthrax contamination episodes of several years ago.

I am here today to speak on the possibility of intentional biological contamination of aircraft cabin atmospheres and how that contamination might be detected before it can be spread. My company, Respiratory Management Technology, Inc. ("RMT") was incorporated in 2002 to focus on identifying solutions for the diagnosis of respiratory illness. Since 2002, RMT has expanded its initial focus to include new scientific and technological advancements in the fields of pulmonary disease management, environmental medicine and biosensor technology. In response to these new advances, RMT has created three business divisions to manage its inter-related products.

Currently, RMT is headquartered in Wilmington, Delaware and is performing initial research and development efforts in Morgantown, West Virginia. RMT's three divisions created are the Pulmonary Disease Management Division, Environmental Medicine Division and the Homeland Security Division. RMT's Pulmonary Disease Management division utilizes it's aerosol generation and sensing technology known as "RAPID" (Respiratory Aerosol Pulsed Injection

Delivery) to cost effectively test, diagnose, analyze and even treat lung disease problems that currently effects over 20 million Americans.

RMT's Environmental Medicine Division has developed an aerosol detection system known as the "CODA" (COntinuous Dust Assessment) Monitoring System. The CODA is a spin-off of RAPID technology that helps companies to detect and control the risk of aerosol-related disease in their work force. The CODA consists of a light scattering photometer capable of detecting and classifying concentrations of dangerous airborne particles. The CODA has already proven to be equally sensitive to competitive products at a substantially lower cost.

RMT's third division, Homeland Security, will also utilize CODA's proprietary technology as part of the "Stage Alert" bio-sensor. RMT's forte, the development of aerosol generation and measurement equipment, has been combined with the expertise of several other corporations to formulate this new cost effective method of bio-terrorist attack detection. The Stage Alert is specifically designed to provide the detection capabilities required for today's bio-terrorist attack threat. The technology consists of sensors that allow the rapid, automated and simultaneous identification of a biological agent. The fundamentals of the system have already been tested and work is planned for a fully functional prototype in the coming months. Portions of the system have been incorporated into a project jointly undertaken with Los Alamos National Laboratory and funded by DARPA to provide protection against airborne microorganism attack for frontline troops. This monitoring system breaks the paradigm for threat detection used by many other devices which do not adequately account for the nature of aerosol generation. Any technique specifically designed for the purpose of microbial droplet generation will yield a different, usually narrower, particle size spectrum which, <u>on a number basis</u>, is substantially larger by orders of magnitude than the "normal" background size spectrum. Analysis of the size spectrum thereby reveals the presence of different sources of aerosol and alerts to the introduction and presence of foreign, extraneous, sources to the average background. Flowing particles can be analyzed using light scattering techniques, instantaneously, in order to measure each particle's size. This aerosol spectrometry gives data on both the number and size of particles suspended in an air stream. Research has shown that the mean particle size based on the number distribution is substantially less than one micrometer (figure 1). Thus, generation of particles larger than one micrometer, common for most biological aerosol generation systems, is easily detected against very low background number concentrations in that size range.

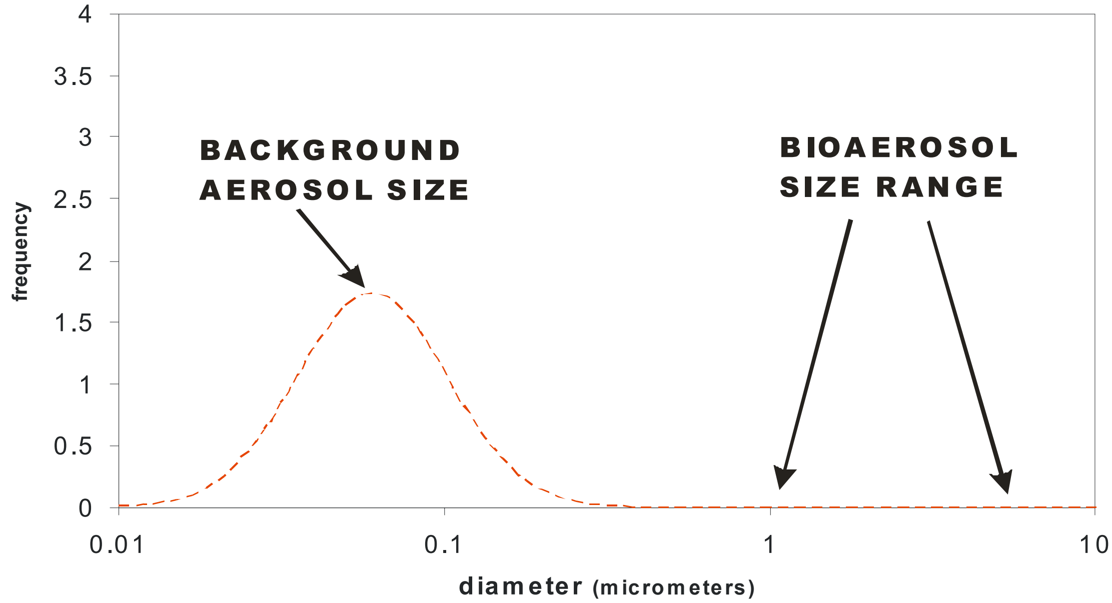

Figure 1. Typical normalized background atmospheric count size distribution, showing the difference between the size of particles expected to be found in the air compared with the much larger size for a generated particle such as would be necessary to disperse microorganisms.

The monitor system consists of three primary autonomous modules, computer controlled, with wireless communication capabilities. <u>The first module</u> (less than 0.1 cubic feet in size) and requiring no maintenance is a light scattering photometer capable of classifying particles between 0.3 and 20 micrometers in size in up to 20 separate size classes, each, one micrometer in width. This is done in real time with constant analysis and storage of the size distribution parameters (geometric mean and geometric standard deviation). This module is able to determine the introduction of a specific narrow size spectrum aerosol at a higher than average particle number concentration. These devices (costing less than $1000 each) could be widely disseminated to alert to the occurrence of a potential attack. In the event of an occurrence a <u>second module</u>, (less than 0.25 cubic feet in volume) consisting of a collection substrate, with only weekly maintenance required for determining the viable component of a sample, employing a fluorescence detector could be used to detect viable material. This module determines whether the amount of overall biologic activity in a particulate sample has increased significantly over previous background samples. It is specific for determining the presence of microbial agents. This second module could be collocated with a <u>third module</u> , either in a fixed location or in a mobile station(less than 0.25 cubic feet in size and costing less than $25,000 for both modules combined) and used for determination of the identity of 20 specific biowarfare agents (BWA), both toxins and microbial pathogens. The third module, in association with the other two modules, allows evaluation of the threat matrix by means of logic that determines: a significant increase in the overall particle concentration within a short span of time along with a spike in a particular size range within that same short span of time; the presence of increased biologic activity in the collected material during that same time span; and finally, the recognition of certain known biological weapons agents in the air stream. These threat events, taken in the order stated, comprise a “high threat alert” when all modules signal an occurrence simultaneously; a “threat potential” when the first two modules together signal an event or if the third module alone signals an event by itself; and a “threat threshold occurrence” if either one of the first two modules singly signals an event happening.

This same system could be deployed in ventilation systems of buildings or in the ventilation system of commercial air carriers. In airplanes, the introduction of a biological aerosol generator could be accomplished in a pocket-sized, simple and inexpensive form. This generator could silently contaminate hundreds of individuals as well as spread further contamination from their clothes and their subsequent infection. This threat could be immediately detected with either the first stage or the first and second stages of a device like the Stage-Alert. These devices could monitor the re-circulated air within the cabin, sense a potential threat and allow the threat to be assessed immediately and possibly countered by various means. Further evaluation, such as could occur with the third stage of the system positioned at the terminal, might take place once the plane has landed. Passengers could be detained shortly while a sample of the cabin air was analyzed. If results for microorganism contamination were positive and quickly confirmed, suspects could be more easily identified and searched. The cost would be under two thousand dollars per plane for deployment with the more costly means of identification of the specific agent involved located only at the terminals.

Mr. Chairman, this concludes my testimony, and I would be happy to answer any questions you may have.